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## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

## (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03929WOGP	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. PCT/HU2004/000032	International filing date (day/month/year) 07.04.2004	Priority date (day/month/year) 09.04.2003
International Patent Classification (IPC) or national classification and IPC A61K31/4453, A61K31/485, A61P25/08, A61P21/02		
Applicant RICHTER GEDEON VEGYESZETI GYAR RT.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of sheets, as follows:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the opinion</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>		
Date of submission of the demand 21.12.2004	Date of completion of this report 04.03.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - Gitschner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Siatou, E Telephone No. +49 30 25901-327	



INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
  - a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

**Description, Pages**

1-14 as originally filed

**Claims, Numbers**

1-5 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/HU2004/000032

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
  - the entire international application,
  - claims Nos. 5  
because:
    - the said international application, or the said claims Nos. 5 in respect of IA relate to the following subject matter which does not require an international preliminary examination (specify):  
**see separate sheet**
    - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
    - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
    - no international search report has been established for the said claims Nos.
    - the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	<input type="checkbox"/> has not been furnished
	<input type="checkbox"/> does not comply with the standard
the computer readable form	<input type="checkbox"/> has not been furnished
	<input type="checkbox"/> does not comply with the standard

See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/HU2004/000032

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-5
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-5
Industrial applicability (IA)	Yes: Claims	1-4
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.  
**PCT/HU2004/000032**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claim 5 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document/s:

D1: WO 89/05641 A

D2: DATABASE WPI Section Ch, Week 197821 Derwent Publications Ltd., London, GB; Class B03, AN 1978-37512A, & JP 53 040779 A (NIPPON KAYAKU KK) 13 April 1978 (1978-04-13)

1. The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows oral pharmaceutical compositions comprising an anticonvulsant and a potentiating amount of dextromethorphan.

The subject-matter of claim 1 differs from this known compositions in that compound of formula (I) is used as the specific anticonvulsant instead of the ones disclosed in D1. Furthermore, no percentages for the anticonvulsant and the dextromethorphan are disclosed in D1.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

2. The same applies mutatis mutandis for the subject matter of claim 5.

3. The part subject of the present application relating to the treatment of spasticity with the combination product lacks inventive step (Art. 33(3) PCT) for the following reasons:

Document D1 discloses that dextromethorphan acts as potentiator, potentiating the effects of anticonvulsants in combination preparations. The subject matter of claim 1 differs from that of D1, in that tolperisone or eperisone are used as anticonvulsants of choice, instead of the anticonvulsants disclosed in D1.

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Since tolperisone and eperisone, are known central muscle relaxants (see D2), substituting these for the anticonvulsants mentioned in D1 does not involve the exercise of an inventive skill.

4. The part subject matter of the present application relating to the treatment of pain by the combination product of compound (I) and dextromethorphan is considered to involve an inventive step (Art. 33(3) PCT) since no prior art documents discloses the use of these compounds, either alone or in combination, for analgesia treatment.
5. The subject matter of claims 1-4 is industrially applicable (Art. 33(4) PCT).
6. For the assessment of the present claim 5 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.